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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/485,951	02/17/2000	SEISHI KATO	GI6707PCT-US	2545

7590 12/03/2002
AMY E. MANDRAGOURAS, ESQ.
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BOSTON, MA 02109

EXAMINER

CANELLA, KAREN A

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 12/03/2002

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/485,951

Applicant(s)
Kato et al

Examiner
Karen Canella

Art Unit
1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 months MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-9 and 15-17 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-9 and 15-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Response to Amendment

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.
2. Claims 7-9 have been amended. Claim 10 has been canceled. Claims 6-9 and 15-17 are pending and under consideration.
3. The rejection of Claims 6, 7 and 9 under 35 U.S.C. 102(a) as being anticipated by Accession Number LEG9_HUMAN (Database SwissProt, last sequence revision July 15, 1998) is withdrawn in light of applicants submission of the translated foreign priority document.
4. The rejection of claims 7 and 9 under 35 U.S.C. 102(a) as being anticipated by Matsumoto et al (Journal of Biological Chemistry, July 3, 1998, Vol. 273, pp. 16976-16984) is withdrawn in light of applicants submission of the translated foreign priority document.
5. The rejection of claim 7 under 35 U.S.C. 102(e) as being anticipated by Ni et al (US 6,027,916, cited in the previous Office action) is withdrawn in light of applicants amendment of the claim to incorporate the limitation of 30 contiguous amino acid residues.
6. The rejection of claim 7 under 35 U.S.C. 102(b) as being anticipated by Tureci et al (Journal of Biological Chemistry, March 7, 1997, Vol. 272, pp. 6416-6422, cited in the previous Office action is maintained for reasons of record.).

Tureci et al disclose the sequence of human Galectin-9, said sequence having 87, 46 and 42 contiguous amino acid residues of SEQ ID NO:2 (residues 1-87, residues 89 to 134, residues 149 to 269, and residues 271 to 312, respectively), thus meeting the specific embodiment of comprising at least 30 contiguous amino acid residues of SEQ ID NO:3.
7. The rejections of Claims 6-9 and 15-17 under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial asserted utility or a well-established utility, is maintained for reasons of record. The rejection of claims 6-9 and 15-17 under 35

U.S.C. 112, first paragraph is also maintained for reasons of record. Applicant argues that the similarity between the instant polypeptide and human G9 is such that the instant polypeptide will derive utility from G9. This has been considered but not found persuasive. As stated in the previous office action, various Galectins, although sharing sequence identity have divergent functions. Therefore a recitation of Sequence identity does not establish a function for the disclosed polypeptides. If the instant application does not assert a specific, substantial and credible utility which is commensurate with said established function, there is no patentable utility for the claimed polypeptides. Applicant argues that the ability to bind a sugar should be considered a specific, substantial utility. This has been considered but not found persuasive, as sugar binding ability does not provide a nexus for a real world utility. Applicant argues that since 1982 the PTO has issued 16 patents with "sugar-binding" in the claims. The examiner would like to point out that the instant utility requirement was published in the Federal Register Notices on January 5, 2001, patents which issued before that date have no bearing on the utility of the instant application.

Applicant argues that the art recognizes that establishing sequence homology permits the skilled artisan to extrapolate the function of the unknown reference protein from a "reference point". This has been considered but not found persuasive. As stated in the previous Office action, similarity to other Galectins cannot be the basis of establishing a function for the instant polypeptide as Galectins, although similar in structure have widely differing functions.

8. Claims 7, 8, 9, 16 and 17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant argues that the subject matter of the instant claims was set forth on page 10, lines 2 and 16 and page 9 lines 23. Upon review of these citations, it is noted that they are a reiteration of the claim language drawn to non-specific fragments and undisclosed allelic variants. This has been considered but not found persuasive. The claims are

drawn to a genus comprising variant polypeptides. The specification does not teach a number of species of said genus which would be representative of the genus. The claims do not limit the attributes of the claimed genus by a function which would be consistent with a specific, substantial and credible utility.

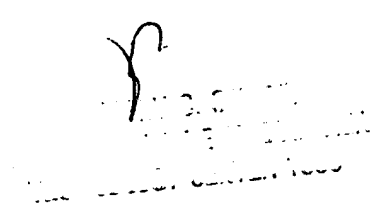
Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.
Patent Examiner, Group 1642
December 2, 2002

A handwritten signature, likely of Karen A. Canella, is written over a circular official stamp. The stamp contains text that is partially obscured by the signature and the date below it.